Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Rm. 1-23
2420 Parklawn Dr.
Rockville, MD 20857

Paul E. Knapp 7432 Hamilton Run Drive Chattanooga, TN 37421

Citizen Petition

The undersigned submits this petition under 21 the Federal Food, Drug, and Cosmetic Act under 21 CFR 5.10; 21 CFR 2.5; 21 CFR 7.41; 21 CFR 7.45(a) and 21 CFR 814.46 to request the Commissioner of Food and Drugs to conduct an evaluation of health hazard and to rescind premarket certification of sunglasses.

A. Action requested

- (1) In accordance with 21 CFR 7.41(a), that the FDA conduct an evaluation of health hazard of the "Radial" sunglasses marketed by and manufactured for Performance Incorporated of Chapel Hill, North Carolina; and,
- (2) In accordance with 21 CFR 814.46, that the FDA withdraw approval of premarket certification (PMA) for sunglasses; and,
- (3) In accordance with 21 CFR 7.45(a) that sunglasses marketed for sport protective use be recalled.

B. Statement of grounds

(1) On February 6, 2000, while mountain biking while wearing a pair of "Radial" sunglasses manufactured for and marketed by Performance Incorporated, of Chapel Hill, North Carolina, I sustained an injury in which my nose was almost completely amputated as a result of an accident (see enclosed post surgical photograph).

The sunglasses are constructed of a polycarbonate material and are a single "wrap around" design that covers both eyes. There is no frame component at the bottom of the glasses that is immediately above the face. The Radial glasses I was

wearing included a prescription glass insert that is available as an option for those who wear prescription glasses. During the accident, the polycarbonate lens was driven into my face during the impact. The shear force and momentum on the unprotected part of the polycarbonate against my face caused the lens to sever my nose at the end of the nose bone. This required approximately three hours of surgical intervention. I reported the incident to the FDA which is in MAUDE report 271570 (see attachment) and notified Performance Incorporated by letter.

It is my experienced opinion that, pursuant to 21 CFR 2.5(a), these sunglasses constitute an imminent hazard to public health, as stated, "... an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held. ... The occurrence of the final anticipated injury is not essential to establish that an imminent hazard of such occurrence exists."

Accordingly, it is requested that the FDA conduct an health hazard evaluation 21 CFR 7.41(a), "An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of the Food and Drug Administration scientists and will take into account, but need not be limited to, the following factors: (1) Whether any disease or injuries have already occurred form the use of the product."

Analysis of Requested Action: When the accident occurred, the trauma of the accident, my concern with administering first aid and getting medical help and the lack of any prescription glasses precluded my ability to ascertain causation. I recalled that the ground in several areas had large rocks and so suspected that it was caused by my face striking a rock on the ground. When I was admitted to the hospital, the asked what had happened and I told them that I thought my face had struck a rock. The hospital and medical information obtained by the insurance company most likely will indicate that the accident was caused by a rock. I visited the scene of the accident and recovered the glasses four days after the accident. I showed the glasses to the surgeon, Dr. Fowler, during a follow-up visit. I pointed out to him my recollection that the wound was "clean," that is, their was no dirt or debris that I would have suspected had the injury been caused by a rock on the ground. I remembered this when I was placing gauze bandages on the wound and noticed an absence of dirt or other debris. I showed him the scratch marks on the glasses that indicated my understanding that that the glasses had amputated my nose. These scratches would not have occurred unless there had been a force and weight (my head) behind them. The surgeon indicated his concurrence with my assessment. I have granted Performance Incorporated access to medical records of this incident through their insurance company, Royal & Sunalliance.

(2) A review of the FDA MAUDE database revealed several reported incidents in which sunglasses are attributed to injuries associated with bicycling accidents (see attachment).

It is noted that in accordance with 21 CFR Part 807.81(b), sunglasses receive an exemption from premarket certification. However, 21 CFR Part 886.9(a) states, "manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use <u>different from the intended use</u> of a legally marketed device in that generic type of device.

Additionally, 21 CFR Part 807.81(a) states, "premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:"

"(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or <u>intended use</u>. The following constitute significant changes or modifications that require a premarket notification:"

"(ii) A major change or modification in the <u>intended use</u> of the device."

The meaning of "intended use" is described in 21 CFR 801.4, "The words intended uses or words of similar import in Secs. 801.5, 801.119, and 801.122 refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised..." As described in the FDA's "Guidance Document for Nonprescription Sunglasses," dated October 9, 1998, "This guidance applies to all Class I nonprescription sunglasses ... worn in conjunction with casual or fashion dress and during general recreational activities. This guidance does not apply to ... sport protective evewear ..."

It is evident that sunglasses are being marketed with a change in intended use for high impact sport protective wear, specifically associated with mountain biking. This practice is contrary to the FDA's intended conditions for use of sunglasses as established through premarket certification. The change in intended use is by means of advertising as exemplified in the attached section of catalogs from Performance Incorporated, Bike Nashbar and Recreational Equipment Incorporated (REI). Both bicycle catalogs appeal to mountain biking, a high impact sport activity. Additionally, the catalogs include photographs of bicyclists wearing sunglasses like those that they market in the catalog. The attached REI in store "product information guide" on sunglasses includes reference to "active sport" use of sunglasses in the discussion on polarization.

Unless PMA is rescinded for sunglasses, the pervasive practice of gross consumer deception in marketing of sunglasses for uses other than those intended will persist as will the concomitant injury to the public. Accordingly, it is requested that premarket certification of sunglasses be rescinded until adequate measures are implemented that will preclude further deception and injury to the public.

Analysis of Requested Action: It is possible that the various sunglass manufacturers have submitted premarket notification of their sunglasses for use is high impact sporting activities. I do not have any information that supports or refutes the status of any such notification. It is suspected that the incidents involving sunglasses represents only a fraction of the actual occurrences, and that other occurrences either were not reported to the manufacturer or by those who were injured.

(3) It is noted that in accordance with 21 CFR 7.45(a), that "The Commissioner of Food and Drugs or his designee under Sec. 5.20 of this chapter may request a firm to initiate a recall when the following determinations have been made: (1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception."

The enclosed advertising material from Performance Incorporated of One Performance Way, Chapel Hill, North Carolina 27514; Bike Nashbar of 4111 Simon Road, Youngstown, Ohio 44512; and Recreational Equipment Incorporated of 1700.45th Street East, Sumner, WA 98390 substantiate the pervasive and gross consumer deception in the use of sunglasses that are intended as casual dress and fashion eyewear and general recreational activities are being market for high impact sport protective eyewear use. The marketing of these sunglasses documents the change of the intended use and constitutes gross consumer deception as specified in 21 CFR 7.45(a).

The search of the FDA MAUDE database that revealed several documented instances in which consumers have sustained injuries requiring when wearing sunglasses for mountain biking and other high impact sports documents that

sunglasses "... presents a risk of illness or injury..." as specified in 21 CFR 7.45(a).

It is evident that there is gross deception in the marketing of sunglasses for sport protective eyewear use which is contrary to the PMA granted by the FDA for sunglasses. Additionally, the FDA has information on an established record of injury to the public associated with the use of sunglasses as sport protective eyewear. In accordance with 21 CFR 7.45(a), the established gross deception of the public and documented risk of injury warrants recall of sunglasses marketed as sport protective eyewear.

Analysis of Requested Action: No countervailing argument has been identified.

C. Environmental impact

None.

D. Economic impact

Not conducted.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signed:

Paul E. Knapp

7432 Hamilton Run Drive

Chattanooga, TN 37421

Phone (work): 423-855-6639 Phone (home): 423-894-7978





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-Other 🧲 - 510(K) 🔻 Listing®

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BRAND NAME PERFORMANCE RADIAL

TYPE OF DEVICE SUNGLASSES

PERFORMANCE, INC.
ONE PERFORMANCE WAY
CHAPEL HILL, NC 27514

DEVICE EVENT KEY 262893 MDR REPORT KEY 271570

EVENT KEY 254606

REPORT NUMBER 271570

DEVICE SEQUENCE NUMBER 1

PRODUCT CODE HQZ

REPORT SOURCE VOLUNTARY
REPORT DATE 03/28/2000

3 DEVICES WERE INVOLVED IN THE EVENT: 123

1 PATIENT WAS INVOLVED IN THE EVENT

DATE FDA RECEIVED 03/28/2000

IS THIS AN ADVERSE EVENT REPORT? NO

IS THIS A PRODUCT PROBLEM REPORT? YES

DEVICE OPERATOR LAY USER/PATIENT

DEVICE NODEL NUMBER RADIAL
DEVICE CATALOGUE NUMBER 37-0081A

OTHER DEVICE ID NUMBER 00-9303A

WAS DEVICE AVAILABLE FOR EVALUATION? YES

PATIENT OUTCOME HOSPITALIZATION

ADVERSE EVENT OR PRODUCT PROBLEM DESCRIPTION REPORT DATE: 03/28/2000 MDR TEXT KEY: 925786 Patient Sequence Number: 1

WHILE MOUNTAIN BIKING, PT HAD AN ACCIDENT AND STRUCK THE GROUND, PT'S HELMET AND RIGHT SHOULD HIT. PT THEN FELT SOMETHING "SLIPPING" OVER THEIR FACE AND FAINTED FOR A SECOND. WHEN THEY 8TOOD UP, PT FELT SOMETHING IN FRONT OF THEIR MOUTH, PT TOOK OFF THEIR GLOVE AND PUT THEIR RIGHT HAND ON IT WHEN THEY PULLED THEIR HAND AWAY, PT FOUND IT WAS COVERED WITH BLOOD. PT DETERMINED THAT THEIR FACE HAD BEEN OUT AND WAS HANGING IN FRONT OF THEIR MOUTH. PT THOUGHT THAT THEY HAD HIT A ROCK AND THAT IT HAD CUT THEIR FACE. PT TAPED GAUZE PADS TO THEIR FACE THEN DROVE 60 MILES TO A HOSP, A SURGEON WAS CALLED IN WHO AFTER 3 HRS OF SURGERY, HAD REATTACHED PT'S FACE. LATER. ON 2/9. PT RETURNED TO THE SCENE OF THE ACCIDENT AND FOUND THE RIKING SUNGLASSES THEY WERE WEARING ON THE SIDE OF THE TRAIL - ALONG WITH THE PRESCRIPTION INSERTS THAT THEY HAD. IN LOOKING AT THE GLASSES, PT REALIZED WHAT THEY HAD SUSPECTED, THAT THE GLASSES WERE DRIVEN INTO THEIR FACE AND HAD CUT OFF THEIR NOSE APPROX FROM CHEEK-TO-CHEEK. THE GLASSES ARE SOLD BY PERFORMANCE, INC. OF CHAPEL HILL, NC UNDER THEIR BRAND NAME, PERFORMANCE "RADIAL" THEY ARE A KNOCK OFF OF THE POPULAR BOLLE AND SMOTH MOAB TYPE GLASSES, THE SUNGLASS COMPONENT WAS SEVERELY SCRATCHED, BUT NOT BROKEN - ITS A WRAP AROUND GLASS THAT HAS NO FRAME COMPONENT ON THE BOTTOM OF THE SUNGLASS PART - SEE THEIR WEB SITE AT WWW.PERFORMANCEBIKE.COM-FROM THE BLOOD ON THE GLASSES AND THE SCRATCHED LENS, PT DETERMINED THAT IT WAS THE SUNGLASS LENS THAT SEVERED THEIR FACE THESE MAY BE "FASHION" TYPE GLASSES, BUT THEY ARE BEING MARKETED FOR USE IN SPORTING EVENTS. PT SPENT THE NIGHT IN THE HOSP, AND MISSED A WEEK OF WORK FOLLOWING THE SURGERY, PT STILL HAS NO FEELING IN THE RIGHT SIDE OF THEIR FACE ABOVE THE LIP BECAUSE THE NERVES WERE SEVERED AS WELL. THE PROBLEM IS PERVASIVE - IT IS APPLICABLE TO OTHER SUNGLASSES THAT DO NOT HAVE A FRAME COMPONENT AT THE BOTTOM, SUCH AS THOSE THAT PERFORMANCE SELLS BY BOLLE AND SMITH.

PATIENT TREATMENT DATA

Date Received: 03/25/2000 Patient Sequence Number: 1

Treatment

Treatment Date

1.OTHER SUNGLASSES THAT HAVE POLYCARBONATE LENS,

2 WITHOUT A FRAME COMPONENT AT THE BOTTOM ARE.

3, SUSPECT FOR INFLICTING THIS SAME TRAUMA -BOLLE,

4.KNIFE EDGE

SMITH MOAB HP

BOLLE BREAK AWAY, ETC.,



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Return to Search			
		01/01/1997 to	

	Print Namo	Este Report Reported
1 BONDET	<u>SMITH</u>	05/25/2000
2 PERFORMANCE, INC.	PERFORMANCE RADIAL	03/28/2000
3 UNKNOWN MANUFACTURER	<u>DERMABRADOR</u>	02/09/2000
4 RAYBAN SUN OPTICS, I	<u>CAT 3000</u>	12/13/1999
5 ALCON LABORATORIES,	<u>ACRYSOF</u>	11/23/1999
BAUSCH & LOMB, INC.	SUNGLASS HANG TAG	07/07/1999
Z BAUSCH & LOMB INC.	<u>RAY-BAN</u>	07/07/1999
UNKNOWN MANUFACTURER	LAX-OPTICS	03/24/1999
BAUSCH & LOMB, INC.	<u>ray-ban</u>	12/07/1998
10 Bausch & Lomb, Inc.	RAY-BAN	12/07/1998
11 Bausch & Lomb, Inc.	RAY-BAN	12/07/1998
12 BAUSCH & LOMB, INC.	RAY-BAN	12/07/1998
13 BAUSCH & LOMB, INC.	RAY-BAN	12/07/1998
14 BONDET	<u>SMITH</u>	09/30/1998
15 YORKTOWNE OPTICAL CO	VISUAL HEALTHWEAR IN	08/26/1998
16 ROSS PRODUCTS DIV/ A	CLEAR EYES CLR SOOTH	02/23/1998
17 BAUSCH & LOMB, INC.	<u>RAY-BAN</u>	01/30/1996
18 BAUSCH & LOMB, INC.	SUN CLOUD	12/04/1997
19 BAUSCH & LOMB INC.	RAY-BAN	10/21/1997
20 BAUSCH & LOMB, INC.	RAY-BAN	10/07/1997
21 BONEDT	<u>SMITH</u>	09/12/1997
22 BONDET	<u>SMITH</u>	09/10/1997
23 BAUSCH & LOMB, INC.	RAY-BAN	08/11/1997
24 BAUSCH & LOMB, INC.	RAY-BAN	08/11/1997
ZÁ BÁUSCH & LOMB, INC.	<u>ray-ban</u>	08/11/1997
26 PAN OCEANIC PRODUCTS	PAN-OCEANIC EYEWEAR	05/22/1997
27 BAUSCH & LOMB INC.	<u>ray-ban</u>	03/03/1997
28 BAUSCH & LOMB, INC.	RAY-BAN	02/28/1997
29 BONDET	<u>SMITH</u>	02/18/1997
30 BAUSCH & LOMB INC.	RAY-BAN	01/10/1997
31 BAUSCH & LOMB INC.	RAY-BAN SUNGLASS	01/10/1997



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BRAND NAME	RAY-BAN
TYPE OF DEVICE	SUNGLASSES
MANUFACTURER	BAUSCH & LOMB, INC. 5335 CASTROVILLE RD. SAN ANTONIO, TX 78227
MANUFACTURER	RAY-BAN SUN OPTICS, INC. 5335 CASTROVILLE RD SAN ANTONIO, TX 76227
DEVICE EVENT KEY	143435
MDR REPORT KEY	147174
EVENT KEY	138158
REPORT NUMBËR	1643383-1998-00001
DEVICE SEQUENCE NUMBER	1
PRODUCT CODE	HQY
REPORT SOURCE	MANUFACTURER
SOURCE TYPE	CONSUMER, HEALTH PROFESS
EVENT TYPE	INJURY
TYPE OF REPORT	INITIAL
REPORT DATE	01/23/1998
1 DEVICE WAS INVOLVED IN THE EVENT	
1 PATIENT WAS INVOLVED IN THE EVENT	
DATE FDA RECEIVED	01/30/1998
IS THIS AN ADVERSE EVENT REPORT?	YE8
IS THIS A PRODUCT PROBLEM REPORT?	NO
DEVICE OPERATOR	LAY USER/PATIENT
WAS DEVICE AVAILABLE FOR EVALUATION?	NO
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
WAS THE REPORT SENT TO FDA?	. NO
DEVICE AGE	NA
EVENT LOCATION	UNKNOWN

IS THE DEVICE SINGLE USE?

NO ANSWER PROVIDED

TYPE OF DEVICE USAGE

PATIENT OUTCOME

UNKNOWN
REQUIRED INTERVENTION
CRIPTION
T89 Pattent Sequence

ADVERSE EVENT OR PRODUCT PROBLEM DESCRIPTION
REPORT DATE: 01/23/1998 MDR TEXT KEY: 445789 Patient Sequence
Number: 1
CONSUMER ALLEGES AN INJURY REQUIRING MEDICAL TREATMENT.
CAUSED BY HIS SUNGLASSES WHEN HE FELL ON HIS FACE WHILE
BICYCLING.
ADDITIONAL MANUFACTURER NARRATIVE
REPORT DATE: 01/23/1998 MDR TEXT KEY: 445791
ACTUAL MFG. SITE COULD NOT BE DETERMINED.

2 of 2



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BRAND NAME	- RAY-BAN
TYPE OF DEVICE	SUNGLASS
BASELINE BRAND NAME	RAY-BAN SUNGLASSES
BASELINE GENERIC NAME	SUNGLASSES
BASELINE CATALOGUE NUMBER	W2219
BASELINE MODEL NUMBER	X-RAY
BASELINE DEVICE FAMILY	NA :
IS BASELINE PMA NUMBER PROVIDED?	
BASELINE PREAMENDMENT?	YES
TRANSITIONAL?	NO
SHELF LIFE(Months)	NA
DATE FIRST MARKETED	05/18/1995
MANUFACTURER	BAUSCH & LOMB, INC. 5335 CASTROVILLE RD SAN ANTONIO, TX 78227
MANUFACTURER	RAY-BAN SUN OPTICS, INC 5335 CASTROVILLE RD SAN ANTONIO, TX 78227
MANUFACTURER CONTACT	RENEE KLUZNIAK 465 PAUL ROAD BOX 478 ROCHESTER , NY 14603-04 (716) 338 -5702
DEVICE EVENT KEY	72342
MDR REPORT KEY	72468
EVENT KEY	68201
REPORT NUMBER	1643383-1997-00003
DEVICE SEQUENCE NUMBER	1
PRODUCT CODE	HQY
REPORT SOURCE	MANUFACTURER
REMEDIAL ACTION	OTHER
EVENT TYPE	INJURÝ

REPORT DATE 02/24/1997

1 DEVICE WAS INVOLVED IN THE EVENT

1 PATIENT WAS INVOLVED IN THE EVENT

DATE FDA RECEIVED 02/28/1997

IS THIS AN ADVERSE EVENT REPORT? YES

IS THIS A PRODUCT PROBLEM REPORT? NÓ

DEVICE OPERATOR INVALID DATA

DEVICE MODEL NUMBER X-RAY

DEVICE CATALOGUE NUMBER W2219

WAS DEVICE AVAILABLE FOR DEVICE NOT RETURNED TO **EVALUATION?** MANUFACTURER

DATE RETURNED TO MANUFACTURER 12/04/1996

IS THE REPORTER A HEALTH YES PROFESSIONAL?

WAS THE REPORT SENT TO FDA? NO

DEVICE AGE NA

EVENT LOCATION UNKNOWN

DATE MANUFACTURER RECEIVED 12/04/1996

18 THE DEVICE SINGLE USE? NO ANSWER PROVIDED

TYPE OF DEVICE USAGE UNKNOWN

PATIENT OUTCOME REQUIRED INTERVENTION

ADVERSE EVENT OR PRODUCT PROBLEM DESCRIPTION

REPORT DATE: 02/24/1997 MOR TEXT KEY: 174822 Patient Sequence

Number: 1

CONSUMER ALLEGES AN INJURY REQUIRING MEDICAL TREATMENT WHEN HE FELL WHILE RIDING HIS MOUNTAIN BIKE

ADDITIONAL MANUFACTURER NARRATIVE

REPORT DATE: 02/28/1997 MOR TEXT KEY: 174825 ACTUAL MFG SITE COULD NOT BE DETERMINED.



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BRAND NAME

TYPE OF DEVICE

BASELINE BRAND NAME

BASELINE GENERIC NAME

BASELINE CATALOGUE NUMBER

BASELINE MODEL NUMBER

BASELINE DEVICE FAMILY

IS BASELINE PMA NUMBER PROVIDED? NO

BASELINE PREAMENDMENT?

TRANSITIONAL?

SHELF LIFE(Months)

DATE FIRST MARKETED

MANUFACTURER

MANUFACTURER

MANUFACTURER CONTACT

DEVICE EVENT KEY

MDR REPORT KEY

EVENT KEY

REPORT NUMBER

DEVICE SEQUENCE NUMBER

PRODUCT CODE

REPORT SOURCE

SOURCE TYPE

EVENT TYPE

TYPE OF REPORT

RAY-BAN

SUNGLASS

RAY-BAN SUNGLASSES

SUNGLASSES

Z0283

LGE MET II

NA

YES

NO

NA

04/08/1986

BAUSCH & LOMB INC. 5335 CASTROVILLE ROAD

SAN ANTONIO, TX 78227

RAY-BAN SUN OPTICS, INC. 5335 CASTROVILLE RD SAN ANTONIO, TX 78227

RENEE KLUZNIAK 465 PAUL ROAD BOX 478

ROCHESTER , NY 14603-0478

(716) 338 -5702

125143

127905

120279

1643383-1997-00008

HQY

MANUFACTURER

CONSUMER, HEALTH PROFESSIONAL

INJURY

INITIAL

REPORT DATE 09/10/1997

1 DEVICE WAS INVOLVED IN THE EVENT

1 PATIENT WAS INVOLVED IN THE EVENT

DATE FDA RECEIVED 10/21/1997

IS THIS AN ADVERSE EVENT REPORT? YES

IS THIS A PRODUCT PROBLEM REPORT? NO

DEVICE OPERATOR LAY USER/PATIENT

DEVICE MODEL NUMBER LGE MET I

DEVICE CATALOGUE NUMBER Z 0283

WAS DEVICE AVAILABLE FOR EVALUATION? YES

IS THE REPORTER A HEALTH
PROFESSIONAL?
YES

THOTESSIUNALY

WAS THE REPORT SENT TO FDA?

DEVICE AGE NA

EVENT LOCATION NOT APPLICABLE

DATE MANUFACTURER RECEIVED 08/29/1997

18 THE DEVICE SINGLE USE? NO ANSWER PROVIDED

TYPE OF DEVICE USAGE UNKNOWN

PATIENT OUTCOME REQUIRED INTERVENTION

ADDITIONAL MANUFACTURER NARRATIVE REPORT DATE: 09/10/1997 MDR TEXT KEY: 373956 ACTUAL MFG. SITE COULD NOT BE DETERMINED.

ACTUAL MFG. SITE COOLD NOT BE DETERMINED.

ADVERSE EVENT OR PRODUCT PROBLEM DESCRIPTION
REPORT DATE: 09/10/1997 MOR TEXT KEY: 373954 Patient Sequence

Number: 1

CONSUMER ALLEGES AN INJURY REQUIRING MEDICAL TREATMENT, CAUSED BY HIS SUNGLASSES WHEN HE FELL ON HIS FACE WHILE BICYCLING.



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BRAND NAME RAY-BAN

TYPE OF DEVICE SÜNGLASS

BASELINE BRAND NAME RAY-BAN SUNGLASSES

BASELINE GENERIC NAME SUNGLASSES

BASELINE CATALOGUE NUMBER 61605 BASELINE MODEL NUMBER **CATS**

BASELINE DEVICE FAMILY NA

IS BASELINE PMA NUMBER PROVIDED? NO

BASELINE PREAMENDMENT? YES TRANSITIONAL? NO

SHELF LIFE(Months)

04/01/1985 DATE FIRST MARKETED

BAUSCH & LOMB, INC. MANUFACTURER 5335 CASTROVILLE RD. SAN ANTONIO, TX 78227

RAY-BAN SUN OPTICS, INC. MANUFACTURER 5335 CASTROVILLE RD

SAN ANTONIO, TX 78227

RENEE KLUZNIAK 465 PAUL ROAD BOX 478 ROCHESTER , NY 14603-0478 (716) 338-5702 MANUFACTURER CONTACT

DEVICE EVENT KEY 110610 MOR REPORT KEY 112678

EVENT KEY 105936

REPORT NUMBER 1643383-1997-00006

DÉVICE SEQUENCE NUMBER

PRODUCT CODE HQY

REPORT SOURCE MANUFACTURER

SOURCE TYPE CONSUMER, HEALTH PROFESSIONAL

EVENT TYPE INJURY

TYPE OF REPORT INITIAL

REPORT DATE	07/21/1997
1 DEVICE WAS INVOLVED IN THE EVENT	
1 PATIENT WAS INVOLVED IN THE EVENT	
DATE FOA RECEIVED	08/11/1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
DEVICE OPERATOR	LAY USER/PATIENT
DEVICE MODEL NUMBER	CATS
DEVICE CATALOGUE NUMBER	W1487
WAS DEVICE AVAILABLE FOR EVALUATION?	YES
DATE RETURNED TO MANUFACTURER	04/11/1997
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
WAS THE REPORT SENT TO FDA?	NO
DEVICE AGE	NA .
EVENT LOCATION	OTHER
DATE MANUFACTURER RECEIVED	07/17/1997
IS THE DEVICE SINGLE USE?	NO ANSWER PROVIDED
TYPE OF DEVICE USAGE	UNKNOWN
PATIENT OUTCOME	REQUIRED INTERVENTION
ADVERSE EVENT OR PRODUCT PROBLEM DES REPORT DATE: 07/21/1997 MOR TEXT KEY: 317 Number: 1 CONSUMER ALLEGES AN INJURY REQUIRING M CAUSED BY HIS SUNGLASSES WHEN FELL WHI	360 Patient Sequence EDICAL TREATMENT,
ADDITIONAL MANUFACTURER NARRATIVE REPORT DATE: 07/21/1997 MOR TEXT KEY: 317 ACTUAL MFG. SITE COULD NOT BE DETERMINE	



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BRAND NAME

TYPE OF DEVICE

BASELINE BRAND NAME

BASELINE GENERIC NAME

BASELINE CATALOGUE NUMBER

BASELINE MODEL NUMBER

BASELINE DEVICE FAMILY

IS BASELINE PINA NUMBER PROVIDED? NO

BASELINE PREAMENDMENT?

TRANSITIONAL?

SHELF LIFE(Months)

DATE FIRST MARKETED

MANUFACTURER

MANUFACTURER

MANUFACTURER CONTACT

DEVICE EVENT KEY

MDR REPORT KEY

EVENT KEY

REPORT NUMBER

DEVICE SEQUENCE NUMBER

REDICE SECRETARY HOM

PRODUCT CODE

REPORT SOURCE

SOURCE TYPE

EVENT TYPE

TYPE OF REPORT

SUN CLOUD

SUNGLASS

SUNCLOUD

BUNGLASSES

42660570

DOCINI

NA

YES

NO

NA

06/21/1995

BAUSCH & LOMB, INC. 5335 CASTROVILLE RD. SAN ANTONIO, TX 78227

RAY-BAN SUN OPTICS, INC. 5335 CASTROVILLE RD SAN ANTONIO, TX 78227

RENEE KLUZNIAK 465 PAUL ROAD BOX 478 ROCHESTER , NY 14603-0478 (716) 338 -5702

133647

136812

128653

1643383-1997-00010

1

HQY

MANUFACTURER

CONSUMER, HEALTH PROFESSIONAL

INJURY

INITIAL

REPORT DATE 11/28/1997

1 DEVICE WAS INVOLVED IN THE EVENT

1 PATIENT WAS INVOLVED IN THE EVENT

DATE FOA RECEIVED 12/04/1997

IS THIS AN ADVERSE EVENT REPORT? YES

IS THIS A PRODUCT PROBLEM REPORT? NO

DEVICE OPERATOR LAY USER/PATIENT

DEVICE MODEL NUMBER DOCINI

DEVICE CATALOGUE NUMBER 42660570

WAS DEVICE AVAILABLE FOR EVALUATION? YES

DATE RETURNED TO MANUFACTURER 09/29/1997

18 THE REPORTER A HEALTH YES PROFESSIONAL?

WAS THE REPORT SENT TO FDA? NO

DEVICE AGE NA

DATE MANUFACTURER RECEIVED 09/29/1997

IS THE DEVICE SINGLE USE? NO ANSWER PROVIDED

TYPE OF DEVICE USAGE UNKNOWN

PATIENT OUTCOME REQUIRED INTERVENTION

ADVERSE EVENT OR PRODUCT PROBLEM DESCRIPTION REPORT DATE: 11/28/1997 MDR TEXT KEY: 408326 Patient Sequence

Number: 1

CONSUMER ALLEGES AN INQUIRY REQUIRING MEDICAL TREATMENT. CAUSED BY HER SUNGLASSES WHEN SHE FELL ON HER FACE WHILE BICYCLING.

ADDITIONAL MANUFACTURER NARRATIVE REPORT DATE: 11/28/1997 MDR TEXT KEY: 408328 ACTUAL MFG SITE COULD NOT BE DETERMINED.



3.5. Fund and thog Administration - the other or the crities and Reducious aid deal.

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Contact Us

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				rch	

BRAND NAME

TYPE OF DEVICE

BASELINE BRAND NAME

BASELINE GENERIC NAME

BASELINE CATALOGUE NUMBER

BASELINE MODEL NUMBER

BASELINE DEVICE FAMILY

IS BASELINE PMA NUMBER PROVIDED? NO

BASELINE PREAMENDMENT?

TRANSITIONAL?

SHELF LIFE(Months)

DATE FIRST MARKETED

MANUFACTURER

MANUFACTURER

MANUFACTURER CONTACT

DEVICE EVENT KEY

MDR REPORT KEY

EVENT KEY

REPORT NUMBER

DEVICE SEQUENCE NUMBER

PRODUCT CODE

REPORT SOURCE

SOURCE TYPE

EVENT TYPE

TYPE OF REPORT

RAY-BAN

SUNGLASS

RAY-BAN SUNGLASSES

ivii wii oonodiodi

SUNGLASSES

20283

LGE MET H

NA

YES

NO

NA

04/08/1986

BAUSCH & LOMB INC. 5335 CABTROVILLE ROAD BAN ANTONIO, TX 78227

RAY-BAN SUN OPTICS, INC. 5335 CASTROVILLE RD 5AN ANTONIO, TX 78227

RENEE KLUZNIAK

465 PAUL ROAD BOX 478 ROCHESTER , NY 14603-0478

(716) 338 - 5702

125143

127905

120279

1643363-1997-00008

1

HQY

MANUFACTURER

CONSUMER, HEALTH PROFESSIONAL

INJURY

INITIAL

REPORT DATE 09/10/1997

1 DEVICE WAS INVOLVED IN THE EVENT

1 PATIENT WAS INVOLVED IN THE EVENT

DATE FDA RECEIVED 10/21/1997

IS THIS AN ADVERSE EVENT REPORT? YES

IS THIS A PRODUCT PROBLEM REPORT? NO

DEVICE OPERATOR LAY USER/PATIENT

DEVICE MODEL NUMBER LGE MET II

DEVICE CATALOGUE NUMBER Z 0283

WAS DEVICE AVAILABLE FOR EVALUATION? YES

IS THE REPORTER A HEALTH YE8

PROFESSIONAL?

WAS THE REPORT SENT TO FDA? NO

DEVICE AGE NA

EVENT LOCATION NOT APPLICABLE

08/29/1997 DATE MANUFACTURER RECEIVED

IS THE DEVICE SINGLE USE? NO ANSWER PROVIDED

TYPE OF DEVICE USAGE UNKNOWN

PATIENT OUTCOME REQUIRED INTERVENTION

ADDITIONAL MANUFACTURER NARRATIVE REPORT DATE: 09/10/1997 MDR TEXT KEY: 373956 ACTUAL MFG. SITE COULD NOT BE DETERMINED.

ADVERSE EVENT OR PRODUCT PROBLEM DESCRIPTION REPORT DATE: 09/10/1997 MOR TEXT KEY: 373954 Patient Sequence

Number: 1

CONSUMER ALLEGES AN INJURY REQUIRING MEDICAL TREATMENT, CAUSED BY HIS GUNGLASSES WHEN HE FELL ON HIS FACE WHILE BICYCLING.



ui Sil Food and Daug Könstechacon - Cercar for Devices and Radidiografi Heat

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REPORT NUMBER

DATE FDA RECEIVED

BRAND NAME SMITH

TYPE OF DEVICE SUNGLASSES

BONDET 29, RUE JJ ROUSSEAU MANUFACTURER 01104 OYONNAX (AIN)

FRANCE **DEVICE EVENT KEY** 71178

MDR REPORT KEY 71283

EVENT KEY 67051

DEVICE SEQUENCE NUMBER

PRODUCT CODE HQY

REPORT SOURCE DISTRIBUTOR

TYPE OF REPORT INITIAL

REPORT DATE 02/14/1997

1 DEVICE WAS INVOLVED IN THE EVENT

1 PATIENT WAS INVOLVED IN THE EVENT

02/18/1997

IS THIS AN ADVERSE EVENT REPORT? NO

DEVICE OPERATOR LAY USER/PATIENT

WAS DEVICE AVAILABLE FOR EVALUATION? NO ANSWER PROVIDED

IS THE REPORTER A HEALTH PROFESSIONAL?

WAS THE REPORT SENT TO FDA? NO

DISTRIBUTOR FACILITY AWARE DATE 02/12/1997

DEVICE AGE 6 MO

EVENT LOCATION OUTDOORS

ADVERSE EVENT OR PRODUCT PROBLEM DESCRIPTION REPORT DATE: 02/14/1997 MDR TEXT KEY: 170357 Patient Sequence

Number: 1

PT WAS WEARING SUNGLASSES WHILE RIDING HIS BICYCLE IN 10/96. HE FELL AND HIT HIS FACE ON THE GROUND BREAKING THE FRAME OF THE GLASSES. HE CUT HIS FOREHEAD AND RECEIVED 8 STITCHES. MFR BELIEVES THE INJURY WAS CAUSED BY THE PERSON

FALLING ON HIS FACE AND NOT BY THEIR PRODUCT.



and hood and thug Administration - Center to Devices and Retioniqual Read-

BRAND NAME	SMITH
TYPE OF DEVICE	sunglasses
NANUFACTURER	BONEDT 29, RUE JJ ROUSSEAU OYONNAX (AIN) FRANCE 01104
DEVICE EVENT KEY	116822
MDR REPORT KEY	119154
EVENT KEY	112057
REPORT NUMBER	119154
DEVICE SEQUENCE NUMBER	1
PRODUCT CODE	HQY
REPORT SOURCE	DISTRIBUTOR
TYPE OF REPORT	INITIAL
REPORT DATE	09/12/1997
1 DEVICE WAS INVOLVED IN THE EVENT	
/ PATIENT WAS INVOLVED IN THE EVENT	
DATE FOA RECEIVED	09/12/1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
DEVICE OPERATOR	LAY USER/PATIENT
DEVICE CATALOGUE NUMBER	SAPC3NSD
WAS DEVICE AVAILABLE FOR EVALUATION?	yes
IS THE REPORTER A HEALTH PROFESSIONAL?	NO ANSWER PROVIDE
WAS THE REPORT SENT TO FDA?	NO
DISTRIBUTOR FACILITY AWARE DATE	09/12/1997
DEVICE AGE	UNKNOWN
EVENT LOCATION	OTHER
PATIENT OUTCOME	REQUIRED INTERVENTI

ADVERSE EVENT OR PRODUCT PROBLEM DESCRIPTION
REPORT DATE: 09/12/1997 MDR TEXT KEY: 340926 Patient Sequence
Number: 1

ON SEPTEMBER 12, 1997 THE DISTRIBUTOR REC'D A LETTER FROM THE COMPLAINANT ADVISING THE DIST. OF THE INJURY. THE COMPLAINANT WAS WEARING SLIDER AB3 SUNGLASSES WHILE RIDING HER MOUNTAIN BIKE. SHE FELL AND HIT HER FACE ON A ROCK. THE NOSE PIECE BROKE OFF AND SHE STATES IT CAUSED A CUT REQUIRING 20 STITCHES. THE DISTRIBUTOR BELIEVES THE INJURY WAS CAUSED BY THE PERSON FALLING ON HER FACE AND NOT BY THE DIST'S PRODUCT.

9/4/00 9:52 PM



O 3. Food and Drug Administration - terms for Devices and Paul stogical Heat

BRAND NAME	SMITH
TYPE OF DEVICE	SUNGLASSES
MANUFACTURER	BONDET 29. RUE JJ ROUSSEAU OYONNAX (AIN) FRANCE 01104
DEVICE EVENT KEY	116166
MDR REPORT KEY	118466
EVENT KEY	111412
REPORT NUMBER	148466
DEVICE SEQUENCE NUMBER	1
PRODUCT CODE	HQY
REPORT SOURCE	DISTRIBUTOR
TYPE OF REPORT	INITIAL
REPORT DATE	00/10/1997
I DÉVICE WAS INVOLVED IN THE EVENT	
1 PATIENT WAS INVOLVED IN THE EVEN	
DATE FOA RECEIVED	09/10/1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT	7 NO
DEVICE OPERATOR	LAY USER/PATIENT
WAS DEVICE AVAILABLE FOR EVALUAT	TON? YES
IS THE REPORTER A HEALTH PROFESS	HONAL? NO ANSWER PROVIDED
WAS THE REPORT SENT TO FDA?	NO .
DISTRIBUTOR FACILITY AWARE DATE	09/10/1997
DEVICE AGE	8 MO
EVENT LOCATION	ÖTHER
PATIENT OUTCOME	REQUIRED INTERVENTION

WEARING SLIDER SL2 SUNGLASSES WHILE RIDING HER BICYCLE.
SHE FELL AND HIT THE GROUND BREAKING THE FRAME OF THE
GLASSES. SHE REC'D A CUT AND REQUIRED PLASTIC SURGERY. THE
DIST BELIEVES THE INJURY WAS CAUSED BY THE PERSON FALLING
ON HER FACE AND NOT BY THE DIST'S PRODUCT.

9/4/00 9:50 PM



the Kerd and leng administration of enter for Devices and Radichegical Hear

BRAND NAME	SMITH
TYPE OF DEVICE	SUNGLASSES
MANUFACTURER	BONDET 29, RUE JJ ROUSSEAU OYONNAX (AIM) FRANCE 01104
DEVICE EVENT KEY	184333
MDR REPORT KEY	189680
EVENT KEY	178300
REPORT NUMBER	189680
DEVICE SEQUENCE NUMBER	1
PRODUCT CODE	HOZ
REPORT BOURCE	DISTRIBUTOR
TYPE OF REPORT	INITIAL
REPORT DATE	09/30/1998
1 DEVICE WAS INVOLVED IN THE EVENT	
1 PATIENT WAS INVOLVED IN THE EVENT	
DATE FOA RECEIVED	09/30/1998
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
DEVICE OPERATOR	LAY USER/PATIENT
WAS DEVICE AVAILABLE FOR EVALUATION?	YES
DATE RETURNED TO MANUFACTURER	09/30/1998
IS THE REPORTER A HEALTH PROFESSIONAL?	NO ANSWER PROVIDED
WAS THE REPORT SENT TO FDA?	NO
DISTRIBUTOR FACILITY AWARE DATE	09/30/1998
DEVICE AGE	6 MO
EVENT LOCATION	OTHER
PATIENT OUTCOME	REQUIRED INTERVENTION

ON 9/30/98 DIST REC'D A LETTER ADVISING OF THE INJURY. PT WAS
WEARING SLIDER SL2 SUNGLASSES WHILE RIDING HIS MOUNTAIN
BIKE. HE FELL AND HIT THE GROUND BREAKING THE FRAME OF THE
GLASSES. HE REC'D A CUT THAT REQUIRED 9 STITCHES. DIST
BELIEVES THE INJURY WAS CAUSED BY THE PERSON FALLING AND
NOT BY THE PRODUCT.



To Food our Coup Admenstration: Continues for Devices and Midlingian Heat

CORPTION E	Return to Search	
Ser Belowe	BRAND NAME	RAY-BAN
contact List	TYPE OF DEVICE	SUNGLASSES
errestelo :	MANUFACTURER	BAUSCH & LOMB, INC. 5335 CASTROVILLE RD. SAN ANTONIO, TX 78227
sionialnity.	MANUFACTURER	RAY-BAN SUN OPTICS, INC. 5335 CASTROVILLE RD SAN ANTONIO, TX 78227
estanten.	DEVICE EVENT KEY	143435
	MDR REPORT KEY	147174
	EVENT KEY	138156
	REPORT NUMBER	1643383-1998-00001
	DEVICE SEQUENCE NUMBER	1
	PRODUCT CODE	HQY
	REPORT SOURCE	MANUFACTURER
	SOURCE TYPE	CONSUMER, HEALTH PROFESSIONAL
	EVENT TYPE	INJURY
	TYPE OF REPORT	INITIAL
	REPORT DATE	01/23/1998
	1 DEVICE WAS INVOLVED IN THE EVENT	
	1 PATIENT WAS INVOLVED IN THE EVENT	
ere rans	BATE FDA RECEIVED	01/30/1998
	IS THIS AN ADVERSE EVENT REPORT?	YES
	IS THIS A PRODUCT PROBLEM REPORT?	NO .
	DEVICE OPERATOR	LAY USER/PATIENT
	WAS DEVICE AVAILABLE FOR EVALUATION?	NO
	IS THE REPORTER À HEALTH PROFESSIONAL?	YES
	WAS THE REPORT SENT TO FDA?	NO
	DEVICE AGE	NA .
	EVENT LOCATION	UNKNOWN
	DATE MANUFACTURER RECEIVED	01/06/1998

TYPE OF DEVICE USAGE

PATIENT OUTCOME

PATIENT OUTCOME

ADVERSE EVENT OR PRODUCT PROBLEM DESCRIPTION

REPORT DATE: 01/23/1996 MDR TEXT KEY: 445789 Patient Sequence

Number: 1

CONSUMER ALLEGES AN INJURY REQUIRING MEDICAL TREATMENT,
CAUSED BY HIS SUNGLASSES WHEN HE FELL ON HIS FACE WHILE
BICYCLING.

ADDITIONAL MANUFACTURER NARRATIVE
REPORT DATE: 01/23/1998 MDR TEXT KEY: 445791

ACTUAL MFG. SITE COULD NOT BE DETERMINED.



U.S. Food and Chirg Administration - Canter for Devices and Radiological Heat Other 510(K) Listing MAUDE PMA Classification, Registration

BRAND NAME	SMITH
TYPE OF DEVICE	SUNGLASSES
MANUFACTURER	BONDET 29, RUE JJ ROUSSEAU OYONNAX (AIN) FRANCE 01104
DEVICE EVENT KEY	270181
MDR REPORT KEY	279162
EVENT KEY	261779
REPORT NUMBER	279162
DEVICE SEQUENCE NUMBER	1
PRODUCT CODE	HOY
REPORT SOURCE	DISTRIBUTOR
TYPE OF REPORT	INITIAL
REPORT DATE	05/24/2000
1 DEVICE WAS INVOLVED IN THE EVENT	
1 PATIENT WAS INVOLVED IN THE EVENT 🛌	
DATE FDA RECEIVED	05/25/2000
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
DEVICE OPERATOR	LAY USER/PATIENT
WAS DEVICE AVAILABLE FOR EVALUATION?	NÓ
IS THE REPORTER A HEALTH PROFESSIONAL?	NO ANSWER PROVIDED
WAS THE REPORT SENT TO FDAY	NO
DISTRIBUTOR FACILITY AWARE DATE	05/21/2000
DEVICE AGE	3 NO
EVENT LOCATION	ÖTHER
PATIENT OUTCOME	REQUIRED INTERVENTION

SUNGLASS WHILE SKIING. THEY COLLIDED WITH A FELLOW SKIER AND FELL, HITTING THEIR HEAD. THE COLLISION AND FALL CAUSED THE GLASSES TO BREAK AT ONE OF THE TEMPLE PIECES. THE PT RECEIVED A CUT THAT REQUIRED 17 STITCHES. IMPORTER BELIEVES THE CAUSE OF THE INJURY WAS THE COLLISION AND FALL AND NOT A DEFECT IN THE PRODUCT.

2 of 2



... 8 Person with Desig Admirate Probability Constant for the vices and the distribusion Health

BRAND NAME	RAY-BAN
TYPE OF DEVICE	SUNGLASS
BASELINE BRAND NAME	RAY-BAN SUNGLASSES
BASELINE GENERIC NAME	SUNGLASSES
BASELINE CATALOGUE NUMBER	Z0283
BASELINE MODEL NUMBER	LGE MET II
BASELINE DEVICE FAMILY	NA .
IB BASELINE PMA NUMBER PROVIDED?	
BASELINE PREAMENDMENT?	YES
TRANSITIONAL?	NO
SHELF LIFE(Months)	NÄ
DATE FIRST MARKETED	04/08/1986
MANUFACTURER	BAUSCH & LOMB INC. 5335 CASTROVILLE ROAD SAN ANTONIO, TX 78227
MANUFACTURER	RAY-BAN SUN OPTICS, INC 5335 CASTROVILLE RD SAN ANTONIO, TX 78227
MANUFACTURER CONTACT	RENEE KLUZNIAK 465 PAUL ROAD BOX 478 ROCHESTER , NY 14603-04 (718) 338 -5702
DEVICE EVENT KEY	125143
MDR REPORT KEY	127905
EVENT KEY	120279
REPORT NUMBER	1643383-1997-00008
DEVICE SEQUENCE NUMBER	1
PRODUCT CODE	нау
REPORT SOURCE	MANUFACTURER
SOURCE TYPE	CONSUMER, HEALTH PROF
EVENT TYPE	INJURY
TYPE OF REPORT	INITIAL

REPORT DATE	09/10/1997
1 DEVICE WAS INVOLVED IN THE EVENT	
1 PATIENT WAS INVOLVED IN THE EVENT	
DATE FDA RECEIVED	10/21/1997
IS THIS AN ADVERSE EVENT REPORT?	YES
IS THIS A PRODUCT PROBLEM REPORT?	NO
DEVICE OPERATOR	LAY USER/PATIENT
DEVICE MODEL NUMBER	LGE MET II
DEVICE CATALOGUE NUMBER	2 0283
WAS DEVICE AVAILABLE FOR EVALUATION?	YES
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
WAS THE REPORT SENT TO FDA?	NO
DEVICE AGE	NA
EVENT LOCATION	NOT APPLICABLE
DATE MANUFACTURER RECEIVED	08/29/1997
18 THE DEVICE SINGLE USE?	NO ANSWER PROVIDED
TYPE OF DEVICE USAGE	ÜNKNOWN
PATIENT OUTCOME ADDITIONAL MANUFACTURER NARRATIVE REPORT DATE: 09/10/1997 MDR TEXT KEY: 37: ACTUAL MFG. SITE COULD NOT BE DETERMINE	
ADVERSE EVENT OR PRODUCT PROBLEM DES REPORT DATE: 09/10/1997 MDR TEXT KEY: 37: Number: 1 CONSUMER ALLEGES AN INJURY REQUIRING N CAUSED BY HIS SUNGLASSES WHEN HE FELL I BICYCLING.	1954 Patient Sequence IEDICAL TREATMENT.



u.S. Tools will Enough demonstration. Center for Devices and May aroused Head

disclaimer	site map	l	about MAUDE	Į	about CDRH
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		imer site map about MAUDE about CD
l Home	Return to Search	
Elams	BRAND NAME	SUN CLOUD
agels	TYPE OF DEVICE	Sunglass
	BASELINE BRAND NAME	SUNCLOUD
ělp 1	BASELINE GENERIC NAME	BUNGLASSES
r <u>zinde</u> v	BASELINE CATALOGUE NUMBER	42660570
	BASELINE MODEL NUMBER	DOCINI
ch fea	BASELINE DEVICE FAMILY	NÁ
	IS BASELINE PMA NUMBER PROVIDED?	NO
	BASELINE PREAMENDMENT?	YES
	TRANSITIONAL?	NO
	SHELF LIFE(Months)	NA .
	DATE FIRST MARKETED	06/21/1995
	MANUFACTURER	BAUSCH & LOMB, INC. 5335 CASTROVILLE RD. SAN ANTONIO, TX 78227
	MANUFACTURER	RAY-BAN SUN OPTICS, INC. 5335 CASTROVILLE RD SAN ANTONIO, TX 78227
	MANUFACTURER CONTACT	RENEE KLUZNIAK 485 PAUL ROAD BOX 478 ROCHESTER , NY 14603-0478 (716) 338 -5702
	DEVICE EVENT KEY	133647
	MDR REPORT KEY	136812
	EVENT KEY	128653
	REPORT NUMBER	1643383-1997-00010
	DEVICE SEQUENCE NUMBER	1 1
	PRODUCT CODE	HQY
	REPORT SOURCE	MANUFACTURER
	SOURCE TYPE	CONSUMER, HEALTH PROFESSIONAL
	EVENT TYPE	INJURY

l of 2

11/28/1997 REPORT DATE

1 DEVICE WAS INVOLVED IN THE EVENT

1 PATIENT WAS INVOLVED IN THE EVENT

12/04/1997 DATE FOA RECEIVED

YES IS THIS AN ADVERSE EVENT REPORT?

IS THIS A PRODUCT PROBLEM REPORT? NO

LAY USER/PATIENT DEVICE OPERATOR

DOCINI DEVICE MODEL NUMBER

42660570 DEVICE CATALOGUE NUMBER

WAS DEVICE AVAILABLE FOR EVALUATION? YES

09/29/1997 DATE RETURNED TO MANUFACTURER

IS THE REPORTER A HEALTH YES

PROFESSIONAL?

NO WAS THE REPORT SENT TO FOA?

NA DEVICE AGE

09/29/1997 DATE MANUFACTURER RECEIVED

NO ANSWER PROVIDED IS THE DEVICE SINGLE USE?

UNKNOWN TYPE OF DEVICE USAGE

REQUIRED INTERVENTION PATIENT OUTCOME

ADVERSE EVENT OR PRODUCT PROBLEM DESCRIPTION

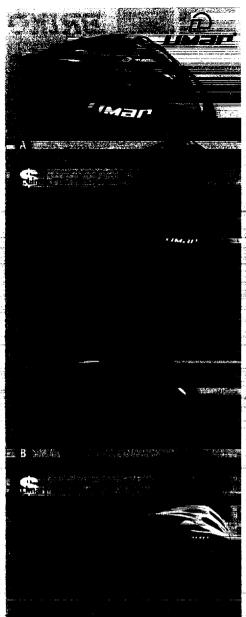
REPORT DATE: 11/28/1997 MDR TEXT KEY: 408326 Patient Sequence

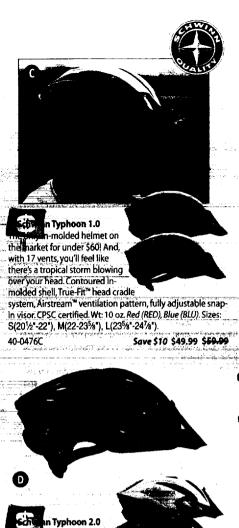
Number: 1

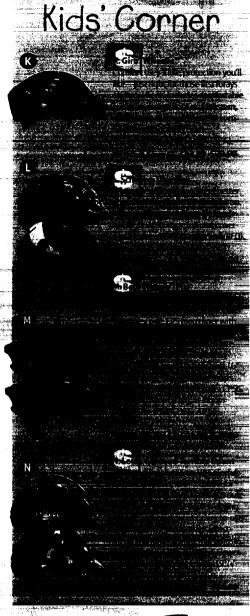
CONSUMER ALLEGES AN INQUIRY REQUIRING MEDICAL TREATMENT, CAUSED BY HER SUNGLASSES WHEN SHE FELL ON HER FACE WHILE BICYCLING.

ADDITIONAL MANUFACTURER NARRATIVE REPORT DATE: 11/28/1997 MDR TEXT KEY: 408328

ACTUAL MEG SITE COULD NOT BE DETERMINED.







Mirrors



E. CycleAware® Reflex™ Mirror Kraton-covered wire is flexible and fully adjustable. Base permanently adheres to helmet, mirror can be detached via ball-andsocket. \$12.99

00-0472A



nSight Mirror irror that won't get in the way. Mounts to any top tube. Adjustable, won't mar bike's

\$12.99 \$14.99 00-8993C



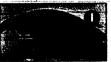
G. Third Eye Eyeglass Mirror Fully adjustable with unique balland-socket design. Installs in seconds and is vibration-free. 37-6642A



L(235/8"-247/8"). 40-0475D

et will stay in place, no matter how rough the trail is. True-Fit™ head cradle system, 13 vents, Airstream™ ventilation pattern,

fully adjustable snap-in visor. CPSC certified. Wt: 11 oz. Red (RED), Silver (SIL), Blue (BLU). Sizes: S(20½-22*), M(22-235/s*),





Gear Mirrors ror fits on the brake hadd. Mountain Mirror fits on to end of flat handlebar, Multi Mirror is fully adjustable and inserts into all flat and drop handlebars (as well as some bar ends). Black. 00-8697C Road \$14.99 \$17.99

Save \$7 \$32.99 \$20.99

00-8696C Mtn. \$14.99 \$17.99 00-8698C Multi. \$14.99 \$17.09

I. CycleAware* ViewPoint™ Mirror

Self-adhesive mirror fits on the inside of your sunglasses and adjusts via a ball-and-socket. 00-0466A

J. Mountain Mirrycle **Bar End Mirror**

37-6651A \$12.99

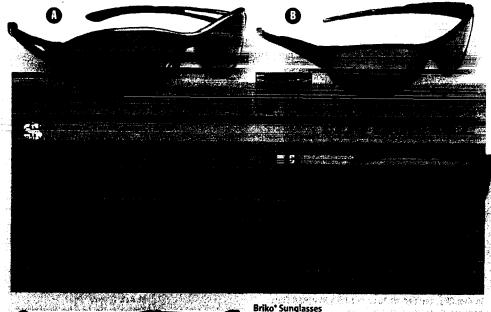


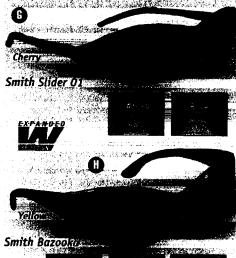
taking comfort and style to new levels. Roc Loc 2 with height adjustment, new lateral adjustment, and ponytail compatibility. 21 fine-tuned vents and unique C-rib technology provide awesome air flow. Bonded Hardbody™ shell, Tri Loc** strap guides and sweat-wicking browpads. CPSC certified. Wt: 10.5 oz. Yellow (YEL),

Carbon (CAR). Sizes: 2XS/XS (201/2"-211/4"), S/M(211/2"-231/2"), L/XL(233/4"-25"). USA.

40-0568C Save \$30 \$69.99 \$99.99

www.performancebike.com





Blue

Smith Mainline

Black

16

Tortoise

Electric Elec

48

Based on Thrama* vision technology, Briko optics selectively filter light in order to drastically reduce visual "noise" and to intensify "signal".

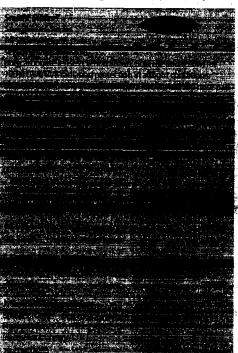
The Thrama* HC Active Plus lenses, best for outdoor sports and medium light conditions, selectively filter blue, red and green to increase contrast. The Thrama' HC 4000 lenses, best for outdoor sports and medium-high light conditions, improve contrast and reduce the dazzling quality of intense light conditions.

All our Briko sunglasses have light, durable Grilamid frames and supports, and Thermolast nosepieces and temple ends that actually slip less the hotter and sweatier you get.

D.-F. Briko' Glasses

Flip colors: Metal Blue (BLU), Black (BLK), Metal Anthracite (TTM). Starter colors; Glossy Brick Red (RED), Glossy Metal Blue (BLU), Matte Black (BLK). Twin Gun colors: Glossy Metal Yellow (YEL), Glossy Metal Red (RED), Glossy Metal Silver (SIL).

20-0555A	Flip w/ HC 4000 Lense Starter w/ Active Plu	\$78.99
20-0556A	Starter w/ Active Plu	\$98.99
20-0557A	Twin Gun w/HC 4000 L	\$88.99





K.-L. Bollé Canebrake Polarized & Piraja Polarized

The Polarized anti-reflective Sandstone lenses provide excellent vision in high-glare conditions. Polarized lenses reduce glare better than any other lens types, and the AR coating eliminates "bounce-back" images. Both styles are made with light, virtually unbreakable Hydralon™ frames, with non-slip Thermo-Grip™ temples and nose pads. The Canebrake has Absorber Hinges to reduce shock and provide an even more comfortable fit. Canebrake frame colors: Black (BLK), Matte Denim (BLU). Piraja frame colors: Black (BLK), Metallic Wine (WIN).

20-0632A Canebrake 20-0631A Piraja

\$99.99 \$99.99

1.800.727.2453

Smith Toaster

Cherry



p profile with a hidden nosepiece, durable composite in frame. Optically correct, shatterproof polycarbonate lenses block 100% UVA/UVB radiation. Lenses are interchangeable. Includes clear lens. Black frame w/Blue Mirror Rayvo lens (BLK) or Silver Metallic frame w/Silver Mirror lens (SIL). Imported. 00-1792D

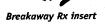
Save \$5 \$24,99 \$29.99

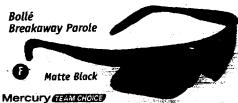
D. Nike Interchang Sunglasses Wrap frames with a rubber-

ized, ventilated nose bridge to minimize fogging and keep the glasses from slipping when you sweat, and secure wrap temples. Wide-wrap 9-base lenses increase coverage for minimal light leakage, and the lenses block 100% UVA/UVB radiation. Includes two sets of lenses to adjust to changing light conditions: Grey for bright light, Orange for cloudy or hazy conditions. Frame colors: Cargo (OLV), Midnight Navy (NVY), Black (BLK). Italy.

\$99.99 20-0616A Bollé Breakaway Vigilante Iron







E. - F. Bollé Breakaway Vigilante and Parole - Rx

Every Breakaway Sports Eyewear System™ comes with four different sets of lenses, so you'll have the proper tint for every condition. The polycarbonate lenses are de-centered to be distortion-free, and block 100% UV radiation. The Breakaway frame is made of incredibly light, virtually unbreakable French nylon, with a nonslip rubber nosepiece and temple tips for a secure and comfortable fit, Includes carrying case to store and protect your glasses and all the lenses. The Breakaway Parole is styled just like the Vigilante but 15% smaller. Perfect for women or anyone who wants less coverage Frame colors: Matte Black (BLK), Iron (PTR), France.

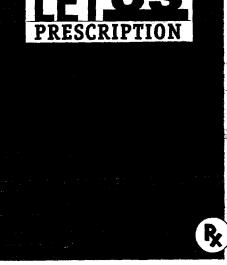
00-4087B	Vigilante	\$109.99
00-4103B	Parole	\$109.99
20-0062A	Breakaway Rx Insert	\$39.99
20-0082A	Vigilante w/Rx Insert	\$129.99
20-0083A	Parole w/Rx Insert	\$129.99

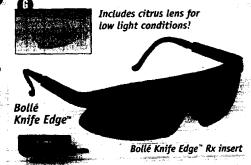
mance" Prism Aurora

sses are designed specifically for cycli s or for those who prefer a sleeker look. Lightweight, rubberized forged nylon frames, Siltec rubber earpieces. Optically correct polycarbonate lenses minimize distortion and block 100% UVA/UVB radiation. Includes grey, amber and clear lenses for best vision in changing conditions, rugged, protective case/cleaning cloth. Black Pearl (SMK).

20-0615B

Save \$10 \$29.99 \$39.99





inife Edge™ - Rx ction from the wind and su價with a low profile.Virtually unbreakable French nylon frame, non-slip rubber nosepiece and temple tips. Knife Edge polycarbonate lens is distortion-free, and blocks 100% UV radiation. Includes a spare Citrus lens for low light conditions and a carrying case to keep everything together. Black frame w/Grey Flash lens (BLK). France.

Suggested retail \$89.99. Save \$60 \$39.99 \$99.99 20-0156E Knife Edge 37-0113A Rx Insert \$29.99

20-0157C

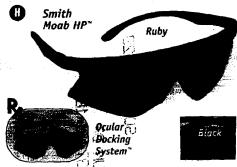
Knife Edge/Rx Insert

nce" Radial" - Rx

sun (and wind and dirt and bugs) out of your eyes with popular glasses. Blue Mirror Rayvo™ lens gives 13 layers rotection and blocks 100% UVA/UVB radiation and reflected glare. Optically correct, shatterproof polycarbonate lens with scratch resistant coating. Unbreakable nylon frames have adjustable temples (standard and cable type both included) and browpad. Comes with sport leash, deluxe EVA case. Optional prescription adapter (Radial™ Diopter) and replacement lenses also available separately. Lenses are interchangeable for the best vision in changing conditions, and all block 100% UVA/UVB radiation. Black (BLK). Imported.

37-0081B	Radial	Save \$5 \$24,99 \$ 29,99
Radial™ A	ixiliary Lenses:	
37-0042A	Clear, Yellow, or Rose	\$5.99
37-0047A	Rayvo Blue or Gold	\$9.99
Prescription	on Nosepiece	
00-9257B	Radial Diopter	\$29.99
00-9967A	Radial & Diopter	\$49.99





H.Smith® Moab HP™ & Obilar Docking System™-Rx These specs come with three interchangeable lenses, so you'll be ready for every condition; and now you can retrofit the Moab HPM with your prescription with the optional ODS "prescription nose-piece. Durable Grilamid hylon fame with a Softak" competition nosepiece. Hard-coaled polycard onate lens colors: Brown Mirrored, Gold Lite and Clear. Lenges block 100% UVA/UVB radiation. Frame Colors: Ruby (RED), Black (BLK). Italy.

00-9721B Moab HP 14-14 00-4659C HP Ocular Docking Sys 00-7498B Moab HP 4 ODS 00-9103C Repl. Moab Lenses

www.performancebike.com

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\$0-18-00	\$4.89	\$7.89	\$13.39	\$6.75
\$18.01-45.00	\$5.99	\$8.99	\$14.49	\$8.75
\$45.01-\$85.00	\$7.09	\$10.09	\$15.59	\$12.99
\$85.01-150.00	\$8.69	\$11.69	\$17.19	\$17.49
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Regular Shipping: via UPS or US Mail, allow 2-8 business days: 2 Business-day Delivery: no Saturday deliveries

Next Day Air: note Saturday delivery incurs an additional \$10.00 surcharge.

Additional Charges: (1) apply for shipments to AK, HI, Guam, PR and VI -2 Business- day Delivery, (2) Trainers, Workstands, Bike Carriers and other over-size items require additional freight charges.

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TOLL FREE: 1-800-727-2453 to order or 1-800-727-3291 to fax your order.

Payment: Our catalog prices are in U.S. currency. You may use American Express, MasterCard, Visa or Discover Card or mail us a money order or personal check drawn on U.S. funds. See Shipping Charges at

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H. Pearl Izumi Ultrasensor* Short

Originally pioneered by Pearl Izumi in 1981, Stretch Ultrasensor* works to keep you dry and comfortable in two ways: larger yarns next to the skin pull moisture via capillary action to finer yarns on the face of the fabric, and hydrophobic polyester speeds evaporation. The result is the best fitting, most comfortable pair of shorts you've ever owned. Stretch Ultrasensor's shorts, modified eight-panel construction without an inseam, spandex gripper leg openings, bio-SUEDE" Chamois System. Black (BLK). Sizes: S(31), M(33), L(36), XL(39). USA.

00-1746A

l, Pearl Izumi Quest Bib Short

The new Seamless Molded Technology (SMT*) chamois delivers friction-free comfort. With a 3D molded chamois, the shorts fit precisely to your anatomy to eliminate friction, and the Cool-Max* cover wicks moisture to reduce chafing. Durable Pearl Izumi Base Fabric nylon/spandex blend, modified six-panel construction eliminates the center seam, spandex gripper leg openings, brushed PolySENTRIC Mesh bib. Black (BLK). Sizes: S(31), M(33), L(36), XL(39). USA 10-0723C

Save \$5 \$54.99 \$59,99

J. Pearl Izumi Eclipse Mesh Jersey

Summer jerseys don't get much cooler. The combination of a loose fit and airy brushed Poly-SENTRIC* Mesh create maximum airflow and moisture evaporation. Raglan sleeves for full freedom of movement, hidden 50cm zipper, elasticized waist, three rear pockets. New Red (RED), Royal (ROY), Yellow (YEL). Sizes: M(39), L(42), XL(45). USA. 10-0714C

K. Pearl Zumi Ultrasensor Tank

Wear alone when running to stay cooler than with no shirt at all, and wear it under a cycling jersey to increase the movement of sweat to the outer layer. Brushed Ultrasensor® mesh pulls sweat away from your skin and helps speed evaporation. White (WHI). Sizes: S(37), M(39), L(42), XL(45). USÁ.

10-0729B

Save \$5 \$19,99 \$24,99

Save \$5 \$44.99 \$49.99 Looking the

L. Pearl Izumi Sleeveless Jersey

To keep you as comfortable as possible during hot summer rides, Pearl Izumi has combined a PolySENTRIC™ Waffle fabric front with an airy brushed PolySENTRIC™ Mesh back. The front draws sweat away from your skiri, and the mesh back keep the air flowing. Sleeveless, with a hidden 50cm zipper, elasticized waist, three rear pockets. New Red (RED), White (WHI). Sizes: S(37), M(39), L(42), XL(45). USA.

10-0392C



0



B-G. Louis Garneau Ultra Pro Short & Bib

Ultra Airdry moves sweat away from your skin, so you stay dry and chafe-free. The monocoque Ultra-Chamois provides the comfort you need so your legs are the first thing to give. Anatomic fit, eight panel design with no center seam, flatlock seams, leg grippers. The Bib has a Lycra® ripstop upper, the Short has an elasticized waist with drawcord. Black (BLK). Sizes: S(30), M(32), L(34), XL(36), XXL(38). Canada.

10-0884B Short Save \$10 \$69.99 \$79.99 10-0883B Bib Short Save \$15 \$74.99 \$89.99

D-E. Pearl Izumi Microsensor* Short & Bib

The best of both worlds: The latest in fabric technology, and a new chamois with a three-level padding design for optimum comfort. The new seamless Pressure Relief Technology (PRT™) chamois has three levels of padding, for shock absorption where you need it and no bulk where you don't. The centerline channel is designed specifically to relieve pressure on sensitive nerves. Soft hydrophobic cover material stays dry to help eliminate chafing. Stretch Microsensor™ provides a supportive form fit with moisture transfer properties that will keep you bone dry. Modified eight-panel design eliminates the center seam and inseam, spandex gripper leg openings. Black (BLK). Sizes: S(31), M(33), L(36), XL(39). USA.

10-0732A Short

\$99.99

10-0400C Bib Short

\$119.99

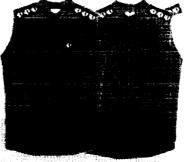








EXPLIZE



PEARL IZUMI MENS SLEEVELESS JERSEY

Pearl Izumi's Sieeveless Jersey uses Polysentric waffle on the front because it is stylish and soft with greater surface area to enhance moisture evapora-tion. Hidden 50cm front zipper, form fit, and three rear pockets for traditional cycling performance Specify Size: S (37), M (39), L (42), or XL (45*); Color: Blue, Red, or White

This jersey is for cyclists preferring a loose-fit jersey. The Ultrasensor* moisture transfer fabric provides optimal comfort and the loose fit provides comfort for all body

types. A hidden Pearl Izumi logo zipper provides tashion-able temperature control. Elastic cuffs and waist for supreme fit. Three back pockets. Specify Size: S (37), M (39), L (42), or XL (45°); Color: Red, Yellow, or Blue.

PI-0527-(size,color)

PEARL OPEN ROAD JERSEY

PI-0595-(size,color)

\$44.95

\$54.95



PEARL BOULDER TEE

The Boulder T is for every active person who seek a higher level of performance than found in a typical t-shirt. Made from Pearl's PolySENTRIC Waffle fabric. with greater surface area to enhance moisture management. Specify Size: S (37), M (39), L (42), XL (45), or XXL (48'); Color: Midnight Blue, Stone, or Forest.

PI-7038-(size,color)

534.95

PEARL DETOUR SHORT

The state of the art in baggy shorts. Designed for functional cycling to lifestyle use. The shell is a durable nylon/cotton blend. External cargo pockets offer ample storage. The liner, a chamois with a Coolina (2021). surface, is removable. Specify Size: S (31), M (33), L (36), or XL (39").

PI-0073-(size)

\$84,95

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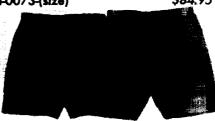
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PEARL RIDEAWAY MEN'S SHORT

This short is a striking, loose-fit cycling short with a func-tional padded liner. Poart Izumi's Ride-Away short outfits the cyclist who demands a fashionable look without sacsthe cyclist who demands a tashionable look wijnout sakan-ficing technical performance. The shell is a soft, texturbed ripstop nylon blend for tightweight comfort and durability. A suspended inner liner uses the SMT**(seamless mold technology) chamois with a CoolMax** surface for a soft moisture transfer function. Zippered side cargo pockets offer convenience and security. Specify Size: S. (31), M. (33), L. (36), or XL. (39*), or XXL. (42) Color: Black/Forest or Black/Platinum.

PI-0080-(size,color)

579.95



PEARL ROCKY ROAD JERSEY Pearl's Rocky Road Top uses soft Polysentric mesh which provides maximum air-flow to speed moisture evaporation and is specifically brushed for incredible comfort. It is a tavorite of offroad enthusiasts because of the 30cm front zipper for temperature control, ragion sleeves, loose fit, and a zippered center back pocket to securely stown essentials. Specify Size: S (37), M (39), L (42), XL (45), or XXL (48'); Color: Blue, Red, or Green.

PI-0582-(size,color)

\$44.95

PEARL MICRO SENSOR SHORT 2000 For the serious cyclist this is Pearl Izumi's most advanced eight panel short Stretch Microfiber fabric offers the latest in fabric fechnology, while the PRT™ chamois is engineered to reduce or eliminate any possible friction points and provide necessary protection in key areas. (The chamois has been used exten sively by the U.S. Postal Service Pro Cycling Team;

Specify Size: S (31), M (33), L (36),

\$99.95

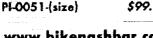


PEARL ULTRA SENSOR SHORT The Ultrasensor® short is Pearl Interpretation of the second o short featuring a stretch Ultrasensor moisture-transfer fabric for a comfortable form fit. The 8 panel design eliminates the inseam and potential pressure points. The BioSUEDE® chamois is contour sewn and provides supple fration control Specify Size: S (31), M (33), L (36), XL (39), or XXL (42°); Color: Black.

PI-0032-(size)

\$74.90







NAA \$31.95 \$36.95 IR-9373 LOW RYDER NV-LR-(color) NV-LR1 Low Rider from 569.90 Our most lightweigh yel durable model to date Equipped with all of the technology needed for you to reach your maximum potentiel. The Low Ryder is also available in a Rash (red) frame with a Black Crystal

refention strap. Imported.

Reliex lens and an Iron (black) frame with a Gray Crystal lens.

INTERCHANGEABLE TEMPLE KIT'M

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Equipped with patented intermenance Keys for switching from The standard temperation

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included)
For use on models with Gator-Lok¹⁹
temples, Byde, Low Ryder, Atheton, and Pro

and nose grips

NANOTM NV-NANO-(color) \$59.90 NV-NANT AL \$49.90 A. TC rdu -:PF r'esit. 409 Spec Tort Blac SM TOA Spe Ros

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\$19.90

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An aerodynamic sungrass featuring steak, interchange able, oval shapped PCC lease of lighting condition. The Nano is also available in an Ale (prown) traine with a Green Crystal lens and an Asphalt (matte black) frame with a Blue Crystal Hoffex lens.

Metal Sky frame Biue Crystal Reflex iens

introducing Native*, an advanced eyewear line made specifically for the arrivere. Each pair of Natives have been engineered for maximum optical protection and centry, so you can perform at the highest level. This has been achieved through state-of-the-art technology that's backed by a Literine Warranty. So if you're locking for comfort technology, and design at a sensible price - get Natives and Sacrifice Nothing.





Low Rider With Rash Color Frame

LENS KITT

NYILK

INTERCHANGEABLE

Orange Polarized Ambe

· A wary many intermandeable lens system which comes in a variety

Available for styles: Nano, Nano: Athelon, and Pro Athelon.

WOMEN'S EXTREME SUNGLASSES

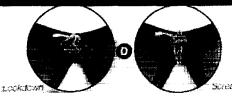
SP-EXT Black front with gray temples: Stue front with gray temples \$38.90 SP-EXT-B

\$38.90



Now it's even quicker and easier to obtain prescription aunglasses. All you need to do is crear this optical adaptor that includes the ISSS 901 labor obta. Then fax or mail us a copy of your prescription from your optician. Be sure that your PD (pupil distance) number is included! After us estable your prescription we will custom make your glasses with high quality potycarbonate materials and aligh tham to you within two weeks. We cannot fill an optical adaptor without a copy of your prescription. Also, we are only able to fill single years prescription. yeur prescription. Also, we single vision prescriptions

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D. EYEGLASS CLIP - Now you can jazz up and personalize your ravonte specs with a solid sterling silver E-Clip! introately detailed. A portion of the manufacturers proceeds are donated to charity. Specify Model: Lookdown or Scream.



E. CHILI'S CROSS-SPORT - Brown shatterproof polycarbonate lens offers better depth perception and contrast Vented design helps prevent folgoing, and rubber temple ups offer an adjustable fit. Imported.

CH-CSP

\$15.90



19.90

19.90

11.90

15.90

SMITH sunglasses are made from the finest and most trusted materials in the industry. The Grilamid® frames are specially formulated for flex, impact resistance and dimensional stability. The rubberized nose piece and temple ends are made from moisture absorbing Megol®, which becomes tacky as you sweat, keeping your glasses comfortably on your face. Smith. Carbonic lenses provide a shatter-resistant front line of defense against dust, flying debris and other airborne irritants. Replacement lenses are available for all lighting

conditions, and all lenses

provide 100% UV protection.

B. BAZOOKA

Comes with Sienna Brown, Gold ith and Yellow replacement lenses. All lenses provide 100% Uv protection. Specify Frame Color: Black, Chrome, Electric Blue, or Kiwi.

SM-BZA-(color) \$98.90

BAZOOKA REPLACEMENT LENS Specify Lens Color: Clear, Rose, Green, Gray or Gray Polarized.

5M-BRL-(color) Polarized

\$19.90 \$47.90



(3)

E. MOAB HP - Provides optimizm vision in varied light conditions, includes Platinum, Gold Lite and Clear replacement lenses. All lenses provide 100% UV protection. Specify Frame Color: Ruby or Black.

CHEELS

SM-MHP-(color)

\$74.90

A PROPERTY AND DEED THE CHARGE IN Gold Life

> MOAB HP REPLACEMENT LENS Specify Lens Color; Platinum Mirror, Gold Lite or Clear. SM-MRL-(color) \$19.90

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PA-SMOP Adaptor(\$49 901+

Fill this adaptor with a pair of your prescription tenses, or let us fill it for

you, and snap them in to the Moab HP classes.

549.90

\$99.80

F. VIGILANTE SES SUNGLASS PACKAGE

D. SMITH MOAB HP

OPTICAL ADAPTOR

SM-MBOP

Adapter only

labor(\$49.90)

This SES (Sports Eyewea: System") package consists of the Vigilante French nylon 9-base wrap frame with uniper rubber nosepiece and temple ends for a secure and comfortable fit, included are four sets of 100%. UV protection polycarbionate lenses. Gun Flash Grey, Vermillion, Crimamon, and Clear, for all riding, conditions. Also included is a cleaning croft bouch that holds the glasses and all of the extra ionses in separate divided sections to protect them from scratches. France Specify Frame Color: Matte Black or Soft Saffron BO-VGT-(color) \$109.90

G. PAROLE SUNGLASSES

rwww.pustaise the Middante, but they are sized down 51, to fit smaller faces. Then thin wind J-base whan frame with proper noteplace is remote too. Includes two onto the electroper and verified in Each Groy and Verifician. Also includes a care the court with morn for Jacobes and extra lenses in range Specify Frame Color. Matte Black or Soft Saffron

BO-PRL-(color)

\$89.90



H. VIGILANTE/PAROLE RX INSERT - Are you tired of not being able to wear sunglasses because you wear prescription glasses? Now you can have the best of both worlds! Have this optical adaptor filled by us or your optician, snap it in either the Vigilante or Parole glasses and you are ready to hit the road. The prescription lenses stay hidden and protected behind the polycartxonate lenses. France

BO-RX \$29.90 Adaptor only **PA-BOP** Adapter(\$29.90) + labor(\$49.90) \$79.80

L PAROLE REPLACEMENT LENSES

Practic kercatement tenses Bendadament tenses designed specifically for the Proble sundlasses. Set of two France. Specify Color: Clear. Cinnamon, Gray. Lemon, or Citrus.

BO-RLP-(color)

\$21.90



experience, minus the

experience, minus me

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Swap stories and tips with ellow cyclists

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Women's technical outerwear

Women's REI Switchback Parka

A hiking and mountaineering favorite, our Gore-Tex® parka stuffs into its own pocket for easy packing.

• Waterproof/breathable 2-layer Gore-Tex®/ripstop nylon protects you from rain, wind and snow.

• Ventilating underarm zippers control airflow.

• Adjustable stowaway hood allows excellent peripheral vision. • Includes drawcord waist and hem, 2 zip chest pockets with

inverted entry, 2 zip handwarmer pockets and an internal pocket.

1 lb. 8 oz. (size M). Imported. Women's S-XL Cactus/slate, Cobalt/black #640-071 \$225





Women's REI Polartec* 200 Jacket

A great value, our high-performance, midweight Polartec® fleece jacket has an open hem for a comfortable fit.

• Moisture-wicking polyester fleece eliminates pilling and insulates even when it's wet.

• Two zip handwarmer pockets. 14 oz. (size M). Made in USA. Women's S-XL Spruce, Black, Ciel blue #640-199 \$60



Women's REI Gore-Tex * Pants

Our lightweight, 2-layer Gore-Tex®/nylon pants offer superior waterproof protection for mountaineering, skiing or backpacking.

- Reinforced seat and knees resist abrasion.
- Elastic drawcord waist; 2 pockets.

Imported. Black. Full-zip pants. Two-way full-length zippers allow easy on/off. Interior gaiters keep snow out. Women's S-XL. Inseam 30" (size M).

#640-573 \$175

Women's Petite S-L. Inseam 27" (size M). #640-574 \$175

Pull-On Pants (not shown) Pull-on style with knee-high side zips.

Made in USA. Women's 6-18. Inseam 31" (size 10). Black #624-150 \$100

Women's REI Polartec* 200 Vest

An excellent layer, our highly breathable Polartec® fleece vest allows full range of motion.

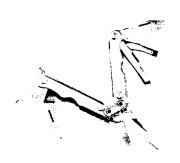
- · Durable midweight polyester fleece is nonpilling and insulates when wet.
- Features microfleece-lined collar, open hem and 2 pockets.

9 oz. (size M). Made in USA. Women's S-XL Black, Ciel blue #647-325 \$45





High-quality 100% UV protection



SOG Cross Cut Tool



- Compound leverage gives twice the gripping/cutting power.
- Locking components keep tool safe and easy to use.
- Includes knife, small and medium screwdrivers, bottle opener, nail file/cleaner, scissors, nylon toothpick, blunt-tip tweezer, lanyard. 2.5" closed; 1.7 oz. Stainless steel. #658-155 \$24



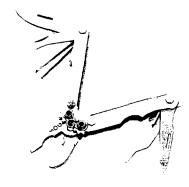
Smith Mainline



Stylish and durable, these sunglasses include 3 interchangeable lenses (brown, gold, yellow) to match varying light conditions.

 Durable nylon frames; nonslip nosepiece and earpieces; scratchresistant polycarbonate lenses; 100% UV protection.

Black, Steel blue, Stone #655-416 \$99



SOG CrossGrip Tool



- Mini-tool with full-size grip and CrossGrip pliers with gear-driven design for maximum leverage.
- Includes knife, small and medium screwdrivers, bottle opener, nail file/cleaner, pliers, nylon toothpick, blunt-tip tweezer, lanyard.
- 2.5" closed; 2 oz. Stainless steel. #652-472 **\$28**



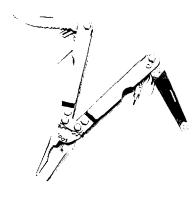
Oakley Minutes



These sleek, wrap-around sunglasses block wind and offer 100% UV protection.

- Shatterproof Plutonite® polycarbonate lenses have Iridium® coating to reduce glare.
- Nylon frames have nonslip rubber earsocks.

Black, Rootbeer, Blue #655-310 \$90



SOG Pocket Power Plier



This plier uses gear-driven compound leverage to provide torque.

• Includes partially serrated blade, Phillips screwdriver, can/bottle opener, fine/coarse metal files, large/small standard screwdrivers, pliers and wire cutters. Handle has measuring scales (metric/standard).

2.5" closed; 2 oz. Includes leather sheath. Stainless steel. #658-162 \$45



Arnette Mantis



These great-looking sunglasses have shatter-resistant polycarbonate lenses that offer 100% UV protection.

 Close-fitting, flexible wireinjected nylon frames.
 Purple #655-501 \$75
 Black, Powder blue #655-502 \$70





Covote PZS-12 Polarized



These casual sport sunglasses are comfortable and stylish enough to wear every day.

- Durable metal frames have spring hinges for a snug fit.
- Copper/gray polarized polycarbonate lenses reduce glare and offer 100% UV protection.
 Antique silver, Antique copper #655-507 \$75

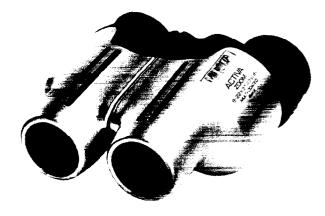


1-800-426-4840

rei stores nationwide

If you think you've seen it all, look again.





These waterproof binoculars use multi-coated optics and BAK-4 prisms to provide sharp images without harmful UV rays.

- 270' field of view at 1,000 yards.
- Soft rubber dust covers flip out to block sunlight and glare from any direction.
- Includes neoprene case, belt attachment, shoulder strap, lens cloth and cleaner.

4¾" x 3¾" x 7¾"; 12 oz. #653-594 \$220

Minolta Activa Zoom 8-22 x 27 Binoculars

Amplify your view by zooming from 8-power to 22-power magnification. Simply use your thumb to focus the zoom control up close or for a wider angle.

- 222'-131' field of view at 1,000 yards.
- Features multi-coated optics, BAK-4 prism, tough rubber body, case and strap.

43/8" x 21/8" x 45/8"; 10.8 oz. #631-973 **\$200**

REI 8 x 21 Armored Monocular

This monocular is so compact

it slips easily into your pocket.

long-lasting outdoor use.

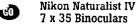
3½" x 1½"; 3 oz. #609-680 \$40

• Rugged rubber-armored body

and clear-roof prism optics provide

• 367' field of view at 1,000 yards.

Includes belt pouch, wrist strap.



at 1,000 yards.

rubber body.

Enjoy the wide wide world with

• Multi-coated optics and Porro

prisms provide crisp, clear,

distortion-free vision.

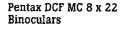
these binoculars' 472' field of view

• Includes 11.8mm eve relief for use

with glasses and a shock-resistant

41/8" x 43/4"; 1 lb. 8.3 oz. #651-570 \$120







These handy, high-contrast binoculars fold up to fit easily into your pocket or pack.

- 330' field of view at 1,000 yards.
- High-resolution phase-coated BAK-4 roof prisms transmit true, bright colors.
- Includes extra-long 17mm eye relief for use with glasses, carrying case, lens caps and strap. 4%" x 4%"; 10.6 oz. #651-577 \$225

Carson Raven 8 x 21 Binoculars



Stash these tiny binoculars in your pocket or pack for clear, stable viewing.

- 373' field of view at 1,000 yards.
- High-contrast multi-coated lenses and BAK-4 prisms provide bright, crisp images.
- Includes 13mm eye relief and roll-down eyecups for glasses, pouch, lens caps and strap. 3%" x 3" x 134"; 5.5 oz. #656-152 \$75









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Sunglasses

product information guide



For the latest info, visit our website

www.rei.com

To ensure maximum protection for your eyes, REI carries only sunglasses that effectively block 100% of UV light. The sunglasses you'll find at REI also block varying amounts of visible light, reducing strain and fatigue on your eyes and making it easier to focus properly.

Lens Material

Lens material has an effect on optical clarity, as well as weight and price. Glass is found in lenses with the highest level of optical clarity and scratch resistance, but it also carries a higher price. Polycarbonate is a notch below glass in optical clarity and scratch resistance, but it's lighter in weight, virtually shatterproof and less expensive. (All lenses, regardless of material, must pass tests for shatter resistance.) Borosilicate and mineral glass are ultra-durable and nearly as lightweight as polycarbonate. Acrylic is lower in both optical clarity and durability than other plastics, but it also costs less.

Tint

Gray, green and brown tints are color-neutral, meaning they will render colors true. That makes them a popular choice for general outdoor use or driving. Rose, gold and amber tints enhance contrast, making them well-suited to low-light conditions. That makes them a fine choice for skiing or cycling on cloudy days.

Polarization

Polarized lenses incorporate a special filter to block flat reflected light, such as that off snow, glass or water. These lenses reduce glare, which is important for mountaineering or paddling. They also reduce contrast, though, making them less suited to active sports like skiing because they make it difficult to read terrain when it's cloudy.

Light Transmission

Light transmission tells you how dark the lens is—the lower the number, the less visible light passes through the lens. This is especially important on glacier glasses because prolonged exposure to sun at high altitude can cause snow blindness. Most glacier glasses feature lenses that allow no more than 10% of visible light to pass through. For general use, around 15-25% light transmission is standard. Photochromatic lenses vary their darkness according to existing light conditions—they darken when it's sunny, and get lighter as the clouds roll in.

Frame and Hardware

Frame materials include metal, nylon and acetate. Metal frames are easily adjusted to your face. Nylon frames are generally more durable and less expensive, but cannot be adjusted to your face unless they have a flexible wire core inside. Some names of high-quality nylons are Grilamid and O Matter™. These and acetate frames have a smooth, comfortable feel because they have been "tumbled" to remove ridges and seams left over from the molding process. On less-expensive nylon frames, the hinges are molded into the frame. High-quality frames have durable nickel-silver hinges,

Fit

Your sunglasses should fit snugly on the nose and ears, with the weight evenly distributed between those three points. On a metal frame, the nosepiece can often be bent inward or outward to fit your nose better. Both metal and wire-core temples can also be bent to conform to the shape of your head and ears. That will give you a more comfortable fit and help keep your sunglasses in place.

Products and prices vary. For the latest info, visit www.rei.com at an in-store kiosk or at home.

	item #	Lens Material	Tint	Light Transmission	Additional Lenses	Frame Material	Price
Shields—feature a single lens and wrap	far around you	ır face, offering maximu	m sun and wind protectio	n for cycling, skiing or other f	ast-moving activ	rities	
Smith Moab	409-163	Polycarbonate	Gray, Gold, Clear ²	Gray—15%, Gold—54%	Included	Nyton	\$ 49.95
Smith Moab H/P	611-109	Polycarbonate	Gray, Gold, Clear ²	Gray—15%, Gold—54%	Included	Grilamid nylon	\$ 74.95
Smith Boomerang	638-004	Polycarbonate	Brown, Gold, Clear?	Brown—18%, Gold—15%	Included	Grilamid nylon	\$ 84.95
Dakley M Frame Strike	646-965	Plutonite® plastic	Gray	24%	Optional	O Matter™ nylon	\$100
Dakley M Frame Heater	646-966	Plutonite® plastic	Gray	24%	Optional	O Matter™ nylon	\$100
Oakley M Frame Sweep	646-968	Plutonite® plastic	Gray	24%.	Optional	O Matter™ nylon	\$100
Oakley Pro M Frame Heater—Iridium®	623-792	Plutonite® plastic	Black Iridium (gray) Gold Iridium (amber)	Black—9% Gold—11%	Optional	O Matter™ nylon	\$140
Oakley Pro M Frame Strike—Iridium®	623-793	Plutonite® plastic	Black Iridium (gray) Gold Iridium (amber) Red Iridium (gray)	Black—9% Gold—11% Red—15%	Optional	O Matter™ nylon	\$140

Smith Ocular Docking System

Shield Accessories

623-790 Fran

Frameless prescription eyeglass adapter—fits Smith Moab H/P and selected Smith ski goggles only

\$ 49.95

²These come with 3 interchangeable lenses.

Products and prices vary. For the latest info, visit www.rei.com at an in-store kiosk or at home.

	item #	Lens Material	Tint	Polarized	Light Transmission	Frame Material	Cable Temples ¹	Metal Hinges	Price
Glacier Glasses—designed for use		and the second s							
REI SP Glacier	611-184	Glass	Amber	No	10%	Nylon	Yes	No	\$ 36
REI Polarized SP Glacier	611-185	Glass	Gray	Yes	5%	Nylon	Yes	No	\$ 52
REI Karakorum Polarized Glacier	611-253	Glass	Gray	Yes	5%	Nylon	No	No	\$ 60
Bollé Glacier	643-827	Polycarbonate	Amber	No	16%	Nylon	Yes	No	\$ 36
Cebe 2000 Glacier	645-794	Polycarbonate	Brown	No	4-6%	Polycarbonate	No	Yes	\$ 90
Cebe Special Mountaineering	624-216	Mineral glass	Green	No	6%	Metal	Yes	Yes	\$100
Cebe 4000 Cecchine! II	409-031	Mineral glass	Green	No	6%	Metal/nylon	Yes	Yes	\$125
Julbo Drus	638-641	Polycarbonate	Brown	No	12%	Steel	Yes	Yes	\$ 79
Julbo Atlas—Blue Ecran	616-248	Polycarbonate	Gray	No	7%	Metal	Yes	Yes	\$ 79
Juibo Micropore Polycarbonate	628-583	Polycarbonate	Brown	No	13%	Metal	Yes	Yes	\$ 89
Julbo Altitude Arc-Round	616-249	Glass	Amber	No	4%	Metal	Yes	Yes	\$ 93.5
Junior Glacier	409-038	Polycarbonate	Gray	No	15%	Plastic	Yes	No	\$ 7
Wraps-wrap around your face, of	fering increas	ed wind and sun prot	ection						
rnette Catfish	611-114	Polycarbonate	Gray		13%	Nylon		Yes	\$ 65
Armette Ravon	610-949	Polycarbonate	Gray		13%	Nylon		Yes	\$ 75
Arnette Raven - Polarized	623-577	Glass	Gray		15%	Nýlon		Yes	\$140
Coyote PZ-1 Polarized	630-754	Polycarbonate	Gray		15%	Nylon		No	\$ 69
Coyote PZ-2 Polarized	630-757	Polycarbonate	Copper Rose	· · · · · · · · · · · · · · · · · · ·	19%	Nylon		No	\$ 69
Coyote PZ-8 Polarized	638-049	Polycarbonate	Copper Rose		19%	Nylon		Yes	\$ 69
Dakley Fives	623-870	Plutonite® plastic	Gray		24%	Nylon		No	\$ 60
Dakley Iridium® Fives	623-869	Plutonite® plastic	Gold Iridium		11%	Nylon		No No	\$ 70 \$ 60
Dakley Frogskins	622-309 622-311	Plutonite® plastic Plutonite® plastic	Gray Gold Iridium	(amher)	24% 11%	Nylon Nylon		No No	\$ 70
Dakley Iridium® Frogskins Dakley Iridium® Tens	639-124	Plutonite® plastic	Black Iridium	<u> </u>	9%	Nylon		No	\$ 85
Daries intribute tens	003-124	i iutomite piastie	Gold Iridium		11%	,			*
Dakley Iridium® Eye Jackets	609-062	Plutonite® plastic	Gray		24%	O Matter™ nylo	n	No	\$ 90
Dakley 0.4 Squared	647-116	Plutonite® plastic	Gray		24%	O Matter™ nylo	n	No	\$ 95
Dakley Straight Jackets	615-732	Plutonite® plastic	Gold Iridium	® (amber)	11%	O Matter™ nylo	าก	No	\$100
mith Southbound	646-718	Borosilicate glass	Gray		15%	Zyl nylon		Yes	\$ 70
mith Ambush	611-108	Borosilicate glass	Brown		18%	Grilamid nylon		Yes	\$ 94.
Smith Bazooka	623-786	Polycarbonate	Brown, Gold	, Yellow ²	Brown-18%, Gold-54%, Yellow-73%	Grilamid nylon		Yes	\$ 94.
Smith Buzzsaw	629-911	Polycarbonate	Brown, Gold	, Yellow ²	Brown-18%, Gold-54%, Yellow-73%	Grilamid nylon		Yes	\$ 94.
Smith Flipside	638-832	Glass	Brown		18%	Grilamid nylon		Yes	\$ 94.
Smith Otis	619-014	Borosilicate glass	Brown		18%	Nylon		Yes	\$ 94.
Smith Slider SL2	613-778	Polycarbonate	Brown, Gold	, Yellow ²	Brown-18%, Gold-54%, Yellow-73%	Grilamid nylon		Yes	\$ 94.
Smith Slider 01	613-776	Polycarbonate	Brown, Gold	Yellow ²	Brown-18%, Gold-54%, Yellow-73%	Grilamid nylon		Yes	\$ 94.
Smith Zipper	646-719	Borosilicate glass	Brown		18%	Grilamid nylon		Yes	\$ 94.
Smith Toaster	646-717	Polycarbonate	Brown, Gold	, Yellow ²	Brown-18%, Gold-54%, Yellow-73%	Grilamid nylon		Yes	\$ 99
Smith Ambush—Polarized	631-605	Borosilicate glass	Brown		15%	Grilamid nylon		Yes	\$149.
Smith Otis—Polarized	619-015	Borosilicate glass	Brown		18%	Nylon		Yes	\$149.
Sport Glasses—designed for all-a	round use								
REI ClassicPolarized	611-277	Glass	Gray		15%	Nylon		Yes	\$ 52
Bausch & Lomb I's 802	629-914	Glass	Gray, Brown		15%	Nylon		Yes	\$ 39
Bausch & Lomb I's 803	630-760	Glass	Gray		15%	Metal		Yes	\$ 49
Bausch & Lomb I's 805	629-913	Glass	Gray, Brown		15%	Metal		Yes	\$ 49
Bausch & Lomb I's 807	638-441	Glass	Gray		15%	Metal/plastic		Yes	\$ 49
Bausch & Lomb I's 808	638-442	Glass	Gray		15%	Metal/plastic		Yes	\$ 49
Bollé 400 PC	643-829	Polycarbonate	Gray		19%	Nylon		Yes	\$ 45
Bollé 401 PC	643-837	Polycarbonate	Gray		19%	Nylon		No .	\$ 40
Bollé 401 PCPolarized	643-839	Polycarbonate	Brown		9%	Nýlon		No	\$ 60
Bollé Coach Whip PC	643-828	Polycarbonate	Gray		19%	Nylon		No	\$ 60
Coyote GP-19	631-597	Glass	Brown, Gray		15%	Acetate		Yes	\$ 39
ossil 350	627-287	Glass	Gray		15%	Metal		Yes	\$ 40
ossil Cayman	637-276	Glass	Gray		15%	Metal		Yes	\$ 45
Fossil Hawk	616-054	Glass	Gray		15%	Zyl nylon		Yes	\$ 45
ossil Catalina	627-285	Glass	Gray		15%	Metal		Yes	\$ 45
Dakley Iridium® Tens	639-124	Plutonite plastic	Gray/Amber		9%/11%	Nylon		No	\$ 85
Dakley E-Wire	609-063	Plutonite® plastic	Gray		24%	Metal		Yes	\$135
Dakley Square Wire	616-395	Polycarbonate	Gray		24%	Metal	**	Yes	\$135
Dakley A-Wires	639-125	Plutonite plastic	Black Iridiun	n® (grav)	9%	Metal		Yes	\$135
Dakley A-Wires—Thick	639-126	Plutonite plastic	Black Iridiun		9%	Metal		Yes	\$135
Ray Ban Outsider	631-591	Glass	Gray	(5)/	15%	Nylon		Yes	\$ 69
Ray Ban Predator II	409-185	Glass	Gray		15%	Nylon		Yes	\$ 80
Ray Ban Predator 8	617-839	Glass	Gray		15%	Metal		Yes	\$ 80
Smith Burnside	636-239	Glass	Brown		18%	Grilamid nylon		Yes	\$ 69.
	JJU -00								
Smith IQ	629-912	Borosilicate glass	Gray, Brown		Gray-15%, Brown-18%	Grilamid nylon		Yes	\$ 69.

¹Hook around your ears to hold your sunglasses securely in place. ²These come with 3 interchangeable lenses. Specifications based on information available at time of publication.

To better serve you, this store's gear is tailored to your area. Some flems have limited availability—for any item not in store, let us help you at Customer Service, by phone (1-800-426-4840) or at www.rei.com.







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